REMARKS

Applicant acknowledges and wishes to thank the Examiner for rejoining Groups I and II pursuant to Applicant's reply filed on May 26, 2006. Applicant notes that the restriction requirement between Groups II and III as product and method of use still stands.

Applicant elected the product claims of Group II (claims 20-29) and that to maintain rejoinder any amendments to the product claims must also be effected in the process claims of Group I (claims 1-19).

Applicant acknowledges the obligation under 37 C.F.R. 1.56 to point out the inventor and the invention dates of each claim that was not commonly owned at the time a later invention was made. The Examiner is correct in presuming that the subject matter of the claims in the present application was commonly owned at the time any inventions covered therein were made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Chen et al.* (U.S. Patent No. 6,383,471) in view of *Gordziel* (U.S. Patent No. 6,287,597).

The Examiner indicates that *Chen et al.* disclose the general teachings of converting an active pharmaceutical ingredient such as gabapentin (see column 6, line 33) into its tannate salt complex (see column 11, line 50) by protonating the basic groups of gabapentin. The Examiner further indicates that the ionizing agent is present in an amount of at least 0.1 mole equivalent per mole of ionizable functional groups (see column 11, lines 56-59). The Examiner, however, acknowledges that the present invention differs from the prior art reference in that the reference fails to disclose addition of dispersing agent, excipients, pH ranges and addition of sweeteners.

Applicant asserts that the *Chen et al.* reference is not relevant prior art to the present application. *Chen et al.* relates only to "ionizable hydrophobic therapeutic

agents" defined in the specification at column 4, lines 53-59, as being compounds with little or no water solubility at neutral pH. Intrinsic water solubilities "(i.e., water solubility of the unionized form) for the ionizable hydrophobic therapeutic agents usable in *Chen et al.* are less than about 1% by weight, and typically less than about 0.1% or 0.01% by weight." Furthermore, claim 1 and every independent claim in the *Chen et al.* patent require that the pharmaceutical composition contain a hydrophobic therapeutic agent with an intrinsic water solubility of less than about 1% by weight. Gabapentin is not hydrophobic and does not have an intrinsic water solubility of less than about 1% by weight at neutral pH. In fact, gabapentin is hydrophilic. The Merck Index, Thirteenth Edition, states that gabapentin has a solubility in water at pH 7.4 which exceeds 10%. *Chen et al.* teach away from using a hydrophilic therapeutic agent such as gabapentin and thus cannot serve to create a prima facie case of obviousness. Clearly, gabapentin was erroneously included in the laundry list of approximately 500 "hydrophobic therapeutic agents" in the *Chen et al.* patent. A copy of the relevant portions of the Merck Index, thirteenth Edition, is attached as Exhibit 1.

With regard to *Gordziel*, as the Examiner indicates, the reference discloses a pharmaceutical composition that comprises: A partial listing of ingredients taken from Example 2 which is a suspension formulation containing Pyrilamine Tannate, and Phenylephrine Tannate. Some of the ingredients disclosed in Example 2 of *Gordziel* are similar to those disclosed in Example 2 of the present invention, i.e., Pectin, Sucrose, Saccharin Sodium, Magnesium Aluminum Silicate, Water, Glycerin and Methylparaben. These are merely typical ingredients that are used in the preparation of conventional suspension formulations. In contrast, the present invention utilizes a dispersing agent such as Magnesium Aluminum Silicate, Xanthum Gum, Kaolin and Pectin, in the gabapentin and tannic acid conversion step to produce a gabapentin tannate dispersion or anti-clumping agent complex. (See page 3, third full paragraph.) Furthermore, *Gordziel* never mentions gabapentin or gabapentin tannate, thus there is no disclosure or suggestion that gabapentin could be effectively incorporated into a tannate salt complex. And, as discussed above, the *Chen et al.* reference is limited to hydrophobic therapeutic

agents which excludes gabapentin and cannot be combined with *Gordziel* to render pending claims 1-29 as being unpatentable under 35 U.S.C. 103(a).

Furthermore, Applicant indicates in the specification of the present application that the formation of a tannate salt of gabapentin is unexpected because of the close proximity of a carboxylic acid group to the amine group. The negative charge on the carboxylic acid group was expected to shield and possibly neutralize the positive charge on the proximal nitrogen. Since tannate salts are thought to normally form through an ionic interaction with a positively charged amine functional group, the close proximity of the carboxylic acid group was expected to prevent the formation of the tannate salt.

Claims 1-4, 6, 8, 10-14, 19-25, 27 and 28 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as claims 1-16 of copending Application No. 10/805,806. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Once patentable subject matter has been determined in the present application, if necessary, claim amendments can be made to overcome the above double patenting rejection.

Claims 1-19 are provisionally rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-9, 12-14 and 18 of copending Application No. 10/806,022 in view of *Gordziel* (U.S. Patent No. 6,287,597). This is a provisional obviousness-type double patenting rejection which may be overcome by a timely filed terminal disclaimer. An appropriate terminal disclaimer is filed with this document.

Briefly to summarize, once *Chen et al.* is withdrawn as relevant prior art, the 35 U.S.C. 103(a) rejection based on *Gordziel* cannot be maintained. Thus, the 35 U.S.C. 103(a) rejection has been overcome and claims 1-29 are patentable.

In conclusion, Applicant asserts that all the pending claims 1-29 meet the formal and substantive requirements of the patent laws and are in condition for allowance.

Accordingly, Applicant respectfully requests early issuance of the formal Notice of Allowance.

Respectfully submitted,

KING & SCHICKLI, PLLC

By: _____
Warren D. Schickli
Registration No. 31, 057

247 North Broadway
Lexington, Kentucky 40507
Phone: (859) 252-0889

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on Nov. 21, 2006.

_____ Date: 11/22/06